Philip Morris International on the Regulation of Potentially Reduced Exposure and Reduced Risk Tobacco Products

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1. INTRODUCTION

1.1 This paper outlines Philip Morris International's ("Philip Morris") views on a regulatory framework for potentially reduced exposure tobacco products in Germany.

1.2 Philip Morris supports tobacco regulation in general. Strong regulation is an effective way to address many concerns raised by the manufacture, sale and use of tobacco products. We firmly believe that regulation offers a long-term solution to tobacco issues that can benefit public health objectives *and* business goals. We therefore are committed to working with the government and public health officials to achieve regulation.

1.3 We also believe that regulation can provide a framework to guide the development, evaluation, marketing and sale of reduced exposure or reduced risk tobacco products. We are committed to developing and responsibly marketing products which have the potential of offering adult smokers reduced health risks as compared to traditional cigarettes. As we have stated many times, smokers are far more likely to develop lung cancer, heart disease, emphysema and other serious diseases. We believe the development of products that have the potential to reduce the risk of those diseases is an important goal for us, for consumers and for public health officials.

1.4 The regulation of reduced exposure products is an important and timely issue. For example, Directive 2001/37/EC requires the Commission to consider the evaluation of tobacco products which may have the potential to reduce harm. In 2001, the United States Institute of Medicine ("IOM"), following a request from the U.S. Food and Drug Administration, issued a report recommending a regulatory framework for reduced risk tobacco products. The World Health Organisation's Scientific Advisory Committee on Tobacco Regulation has also looked at the issue. Moreover, tobacco manufacturers have indicated that

they are developing products that they believe could offer reduced risk – and in some markets, such products have been placed on the market

1.5 In our view, the optimal approach to the development and marketing of such products is for the Government to provide guidance both to manufacturers and to consumers by establishing a specific regulatory framework. This paper therefore outlines our views on the establishment of a regulatory scheme in relation to potentially reduced exposure tobacco products.

1.6 Our use of the term 'potentially reduced exposure products' and our proposals are based on a report issued by the United States Institute of Medicine in 2001 entitled: "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction" (the "IOM Report")[1]. At the request of the U.S. Food and Drug Administration, the IOM, which examines policy matters pertaining to public health and is part of the U.S. National Academy of Sciences, recommended specific steps for the creation of a framework for assessing harm reduction of tobacco products. The Committee created for this purpose was comprised of leading scientists and physicians from around the United States. A list of the Committee members is attached at Annex I. The IOM Report is available on line at: http://www.nap.edu/books/0309072824/html/.

1.7 The IOM Report is an authoritative and thorough analysis of the important issues surrounding the development, marketing and regulation of tobacco products that offer the potential of reducing exposure and risk to individual smokers and the smoking public in general. While it is a document written for the United States government, we believe that, it can be used by governments and intergovernmental authorities around the world to guide their consideration of the regulation of PREPs.

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1 The Report discusses two levels of potentially reduced exposure products, referred to by the English acronym PREPs: (1) products that offer reduced exposure to smoke constituents and (2) products that offer reduced risk of diseases caused by tobacco. In this paper, we refer to both types of products as "reduced exposure products" unless the specific reference makes sense only to one or the other. In the IOM Report, the term PREPs include tobacco and cigarette-like products as well as pharmaceutical products that are used to encourage smoking cessation. However, this paper is concerned primarily with the introduction of a regulatory scheme for tobacco and cigarette-like PREPs rather than PREPs that are already regulated as pharmaceuticals.

1.8 Our paper is divided into three parts. Firstly, we explain why we believe regulation of reduced exposure products is important in the interest of public health and consumer information. Secondly, we set out the regulatory principles that have been recommended by the IOM and which Philip Morris hopes will form the basis of a regulatory framework. Finally, we describe how these principles might be incorporated in a regulatory framework in Germany.

2. IMPORTANCE OF A REGULATORY FRAMEWORK

2.1 Regulation is the optimal approach to the introduction of reduced exposure or reduced risk tobacco products for a number of reasons. First, regulation can ensure that appropriate, valid, reliable and accepted scientific evaluation of the new products is conducted. In that way, consumer, government officials and manufacturers can be assured that the products have the potential of reducing exposure or reducing risk.

2.2 Second, standards governing the claims that may be made about these products are critical. Regulation can ensure that communications made to consumers about the products are accurate and non-misleading.

2.3 Third, regulation can require that manufacturers remind consumers that when it comes to their health and smoking, quitting – not smoking reduced exposure or reduced risk products – is the only safe thing to do.

2.4 While it is our goal to advocate a regulatory framework, achieving regulation, particularly in a new and complex subject matter, is always a time-consuming and difficult process. If such regulation cannot be achieved and we are able to develop products that have a demonstrable potential to offer reduced risk to adult smokers, we believe we should market those products consistent with the principles discussed below.

Appropriate Scientific Evaluation

2.5 Any regulatory scheme – and any decision to introduce a product to consumers as a potential reduced exposure or risk product -- must be based on careful evaluation using consistent, reliable and valid scientific methodology.

2.6 For example, it is vital that these products be subject to rigorous scientific analysis to evaluate the extent to which they reduce exposure to certain constituents and the extent to which that reduced exposure may result in reduced incidence of particular diseases. Existing measurement tools, such as ISO testing methods, are not intended to take account of smoking habits and the ability of smokers to compensate. Therefore Philip Morris believes that in addition to these methods, the scientific evaluation of potentially reduced exposure products should use both *in vitro* and *in vivo* models, and, where possible, conduct exposure and Biomarker assessment in humans. The IOM Report concluded that such scientific testing methods would offer suitable models for evaluating these products.

2.7 Philip Morris hopes that the government, working with the scientific community and tobacco manufacturers, will determine the specific requirements for assessing the potential benefits (and risks) of any new products. Until such standards are developed, we will continue to apply the principles of the IOM Report and best scientific practices to our own internal research and development.

Providing Appropriate Information to Consumers

2.8 Regulation can also provide guidance and assurance concerning communications to consumers about potential reduced exposure and reduced risk products. Consumers should have access to accurate information based on the results of the scientific evaluation and should be able to understand the significance of that information. As the IOM Report states, consumers should be "fully and accurately informed of all of the known, likely, and potential consequences of using these products."[2]

[2] IOM Report at p.7

2.9 Claims in labelling or advertising should be regulated to ensure that the information provided to consumers does not overstate the benefits, nor suggest that quitting is not the best alternative from a health perspective Further, a regulatory scheme can ensure that information about exposure and risk is communicated to consumers on a consistent basis allowing consumers to make an educated assessment of the risk reduction potential of different products.

2.10 Until regulation is passed, existing laws regulating statements made by manufacturers, such as consumer protection laws that prohibit false and misleading advertising, can be used to ensure that claims about reduced exposure and reduced risk products are accurate and not misleading.

Reminding Smokers that Quitting is the only Way to Avoid Risk

2.11 Philip Morris has stated many times that there is currently no such thing as a "safe" cigarette. That is why we believe that manufacturers who market potentially reduced exposure and reduced risk products should emphasise the fact that all smoking is dangerous, and that the best option from a health perspective is to quit or not to start in the first place. Regulation can ensure that messages about reduced exposure or reduced risk products do not encourage people to take up smoking or discourage quitting.

2.12 Finally, a regulatory framework for potentially reduced exposure products should not prevent or deflect government programs to stop smoking. As the IOM Report states: "Harm reduction [should be] implemented as a component of a comprehensive national tobacco control program that emphasises abstinence-oriented prevention and treatment." [3] That is Philip Morris' view as well.

[3] IOM Report at p.7

3. THE IOM REGULATORY PRINCIPLES

3.1 Below we summarise the regulatory principles recommended by the IOM for tobacco products, which apply to both potentially reduced exposure products and conventional tobacco products. Philip Morris believes these principles can help guide a discussion on establishing a regulatory framework for reduced exposure products which is consistent with the existing regulatory framework in Germany. We also use these principles to guide our own views of the proper way to develop and ultimately market potential reduced exposure and reduced risk products.

Regulatory Principle 1. Ingredient Disclosure to Government: Manufacturers of tobacco products, whether conventional or potentially reduced exposure products, should be required to obtain quantitative analytical data on the ingredients of each of their products and to disclose such information to the regulatory agency.

Regulatory Principle 2. Assessment and Communication of Smoke Constituents: All tobacco products should be assessed for yields of nicotine and other tobacco toxicants according to a method that reflects actual circumstances of human consumption. When necessary to support claims, human exposure to various tobacco smoke constituents should be assessed using appropriate Biomarkers. Accurate information regarding yield range and human exposure should be communicated to consumers in terms that are understandable and not misleading.

Regulatory Principle 3. Toxicological Testing of Potentially Reduced Exposure Products: Manufacturers of all potentially reduced exposure products should be required to conduct appropriate toxicological testing in pre-clinical laboratory and animal models as well as appropriate clinical testing in humans to support the health-related claims associated with each product and to disclose the results of such testing to the regulatory agency.

Regulatory Principle 4. Marketing of Potentially Reduced Exposure Products: Manufacturers should be permitted to market tobacco-related products with exposure-reduction or risk-reduction claims only after prior agency approval based on scientific evidence (a) that the product substantially reduces exposure to one or more tobacco toxicants and (b) if a risk reduction claim is made, that the product can reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects, as compared with whatever benchmark product the agency requires to be stated in the labeling. The "substantial reduction" in exposure should be sufficiently large that measurable reduction in morbidity and/or mortality (in subsequent clinical or epidemiological studies) would be anticipated, as judged by independent scientific experts.

Regulatory Principle 5. Advertising and Promotion of Potentially Reduced Exposure Products: The labeling, advertising, and promotion of all tobacco-related products with exposure-reduction or risk-reduction claims must be carefully regulated under a "not false or misleading" standard with the burden of proof on the manufacturer, not the government. The agency should have the authority and resources to conduct its own surveys of consumer perceptions relating to these claims.

Regulatory Principle 6. Post-Marketing Surveillance of Potentially Reduced Exposure Products: The regulatory agency should be empowered to require manufacturers of all products marketed with claims of reduced risk of tobacco-related disease to conduct post-marketing surveillance and epidemiological studies as necessary to determine the short-term behavioural and long-term health consequences of using their products and to permit continuing review of the accuracy of their claims.

Regulatory Principle 7. Continued Marketing of Conventional Tobacco Products: In the absence of any claim of reduced exposure or reduced risk, manufacturers of tobacco products should be permitted to market new products or modify existing products without prior approval of the regulatory agency after informing the agency of the composition of the product and

certifying that the product could not reasonably be expected to *increase* the risk of cancer, heart disease, pulmonary disease, adverse reproductive effects or other adverse health effects, compared to similar conventional tobacco products, as judged on the basis of the most current toxicological and epidemiological information.

Regulatory Principle 8. Toxicological Testing of Ingredients: All added ingredients in tobacco products, including those already on the market should be reported to the agency and subject to a comprehensive toxicological review.

Regulatory Principle 9. Performance Standards: The regulatory agency should be empowered to set performance standards (eg. maximum levels of contaminants; definitions of terms such as "low tar") for all tobacco products, whether conventional or modified, or for classes of products.

Regulatory Principle 10. Enforcement: The regulatory agency should have enforcement powers commensurate with its mission, including power to issue subpoenas.

4. A GERMAN REGULATORY SCHEME

4.1 Philip Morris considers that the Federal Government would be well placed to introduce a regulatory scheme for potentially reduced exposure products in Germany, and indeed for conventional tobacco products, compliant with the 10 principles set out above.[4]

4.2 As an initial matter, many of the actions under a regulatory scheme compliant with the regulatory principles set out above would be carried out by the manufacturer. Such actions would include:

- conducting toxicological review and/or testing in pre-clinical laboratory and animal models of each potentially reduced exposure product and conventional tobacco products (to satisfy Regulatory Principle 3, 7 and 8);

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[4] The IOM established 11 regulatory principles. However, the 11th principle relates to the regulation of PREPs such as nicotine patches. These are currently regulated in Germany under a combination of primary and secondary legislation implementing a number of EU pharmaceutical Directives.

- conducting appropriate exposure studies on humans (to satisfy Regulatory Principle 4);

- conducting ongoing post market surveillance and epidemiological studies to determine the long-term impact of potentially reduced exposure products marketed with claims of reduced risk (to satisfy Regulatory Principle 6);

- where permitted to do so, using specified claims in relation to the potential exposure or risk reducing effect of the tobacco products (under conditions consistent with Regulatory Principles 4, 5 and 9); and

- in relation to new or modified tobacco products for which no reduced exposure or risk claim would be made, certifying that the product "could not reasonably be expected to increase the risk of cancer, heart disease, pulmonary disease, adverse reproductive effects or other adverse health effects, compared to similar conventional tobacco products" (to comply with Regulatory Principle 7).

4.3 Philip Morris believes that a regulatory regime for potentially reduced exposure products could be introduced within the existing and forthcoming framework of regulations and institutions relating to foodstuffs, commodities and tobacco products. The forthcoming *Bundesamt für gesundheitlichen Verbraucherschutz und Lebensmittelsicherheit* (BVL) would be well placed to act as a regulatory agency with regard to these products, whilst the forthcoming *Bundesinstitut für Risikobewertung* (BfR) would be able to provide the necessary scientific criteria for their regulation. The current Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin (BgVV), whose risk assessment and management functions will be transferred to the BfR and BVL respectively, has within its existing remit the safeguarding of public health in respect of, inter alia, tobacco products. The BgVV has also been involved in the development of regulations concerning the ingredients of tobacco products. Philip Morris therefore believes that the

BgVV's successor organisations[5] will be well placed to assume most of the activities referred to in the IOM principles:

- the BgVV is already involved in the existing regulation of tobacco products;
- it has the necessary scientific resources; and
- it already deals with approval and licensing of products , and would thus be equipped to handle approvals for the tobacco industry, e.g. approvals of low-risk products (Regulatory Principle 4).

Within a regulatory scheme for potentially reduced exposure products, the functions of the BfR could include:

- reviewing toxicological data supplied to it by tobacco manufacturers in relation to ingredients;
- carrying out tests or reviewing test data in relation to tobacco constituents provided to it by tobacco manufacturers;
- Based on evidence provided by tobacco manufacturers, a review by independent scientific experts authorising the use of reduced exposure or reduced risk claims in relation to potentially reduced exposure products;
- carrying out and reviewing epidemiological studies in relation to the benefits of potentially reduced exposure products;

The functions of the BVL could include:

[5] Philip Morris recognises that at the time of writing, the *Gesetz zur Neuorganisation des gesundheitlichen Verbraucherschutzes und der Lebensmittelsicherheit* has not yet received approval in the *Bundesrat*. Should the anticipated restructuring of the federal consumer health protection institutions not be consummated, the proposed regulatory functions in respect of PREPs outlined herein could equally be performed by the BgVV.

- co-ordination of the supervision and enforcement by the [Germany to insert correct authority] of the requirements imposed on producers under the regulatory scheme.

4.4 Regulations which would need to be adopted through changes in the existing law would include provisions regarding:

- Approval of health related claims.
- Strict testing and evaluation requirements for tobacco manufacturers.
- A restriction on claims that may be made in relation to products that are not approved as potentially reduced exposure products.
- Uniform labelling requirements for those potentially reduced exposure products in relation to which the government permits a claim to be made.
- Sanctions for failure to comply.

4.5 As noted above, many of the IOM principles are already required under EU Directive 2001/37. In particular, the requirement for manufacturers to provide the German authorities with information on ingredients, including toxicological data, on a product-by-product basis, contained in Article 6 of Directive 2001/37 is consistent with the regulatory principles 1 and 8. Further, Articles 3 and 4 of Directive 2001/37 (in relation to the yield levels of tar, nicotine and carbon monoxide, and the testing of other smoke constituents) can serve as a preliminary step under IOM regulatory principles 2 and 9. Finally, the Directive recognises the issue of potentially reduced exposure products and suggests that this is an issue that should be considered for regulation. For example, in Preamble 8, the Directive states that regulations should "evaluate evidence-based claims for tobacco products designed and/or marketed to "reduce risk", or for which harm reduction is claimed by the manufacturers." The Committee established under Article 11 of the Directive is also tasked to look into the issue and must "pay special heed to," among other things, the "evaluation of tobacco products which may have the potential to reduce harm." Clearly, the Directive views harm reduction as a valid issue

for tobacco regulation. Philip Morris believes it is important for all EU governments to act now to address this matter.

5. CONCLUSION

5.1 Philip Morris is committed to developing and marketing products that may offer adult smokers reduced risk as compared to conventional cigarettes. We hope that the government will play an integral part in this process. We would urge the Federal Government to give serious consideration to the proposals contained in this paper and would welcome the opportunity to meet with the Government to discuss, among other things, our views of the scientific bases for the development and regulation of potentially reduced exposure products.